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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/688,759

10/17/2003

Santosh R. D'Mello

119166-1100

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EXAMINER

WILLIAMS, LEONARD M

ART UNIT

PAPER NUMBER

1617

MAIL DATE

DELIVERY MODE

05/01/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |  |                                       |  |
|------------------------------|--|---------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/688,759   | <b>Applicant(s)</b><br>D'MELLO ET AL. |  |
|                              | <b>Examiner</b><br>LEONARD M. WILLIAMS | <b>Art Unit</b><br>1617               |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 August 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 1-11, 13 and 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12, 14-15 and 17-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>01/03/2006, 01/16/2004</u> .                                  | 6) <input type="checkbox"/> Other: _____                          |

Detailed Action

***Election/Restrictions***

Applicant's election without traverse of Group II in the reply filed on 08/01/2007 is acknowledged. Applicant's have withdrawn claims 1-11, 13 and 16, amended claim 15 and added new claims 17-27 that read on the elected group.

Claims 12, 14-15 and 17-27 are currently pending.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12, 14-15 and 17-27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating neuronal cell death in a mammal comprising administration of GW5074 (hereafter GW) and ZM336372 (hereafter ZM), does not reasonably provide enablement for preventing or inhibiting neuronal cell death in a mammal comprising administration of GW5074 (hereafter GW) and ZM336372 (hereafter ZM). In the broadest reasonable interpretation of the terms preventing and/or inhibiting, complete prevention and/or inhibition is within the scope of the claims. Additionally the claims are drawn to all C-Raf inhibitors while exemplifying

only two. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdAplis 1986) at 547 the court recited eight factors: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

**(1) The Nature of the Invention:**

The rejected claims are drawn to a method of preventing or inhibiting neuronal cell death in a mammal.

**(2) Breadth of the Claims:**

The instant claims embrace a method of preventing or inhibiting neuronal cell death in a mammal that given its broadest reasonable interpretation includes complete prevention and/or inhibition of neuronal cell death in a mammal and encompasses any C-Raf inhibitor.

**(3) Guidance of the Specification:**

The guidance of the specification as to a method of preventing or inhibiting neuronal cell death in a mammal comprising administration of GW5074 (hereafter GW) and ZM336372 (hereafter ZM) is lacking. The specification includes only in vitro data of two compounds (GW5074, hereafter GW; and ZM336372, hereafter ZM) and in a rodent model of Huntington's disease. Figures 1A-D are asserted to show the neuroprotective effects of GW in LK-induced apoptosis. The data presented does not indicate complete prevention and/or inhibition of apoptosis (cell death) in the in vitro model. In Figures 7A-C it is shown that GW's effects are mediated via Nf-kB. Figures 9A-B demonstrate GW reduces the amount MPP+ and methylmercury-induced cell death. Complete prevention and/or inhibition of neuronal cell death in a mammal is not demonstrated. Figures 10A-C show brain lesions in an in vivo experimental model of Huntington's disease. Applicant's assert that the figures demonstrate complete prevention of neurodegeneration. The figures seem only to indicate a reduction of the extensive bilateral striatal lesions induced by 3-NP with no data to quantify or qualify the data shown.

**(4) Working Examples:**

Applicant does not provide any working examples for the prevention and/or inhibition of neuronal cell death in a mammal.

**(5) State/predictability of the Art:**

The state of the art regarding treating neuronal cell death in a mammal is relatively high. However, the state of the art for prevention and/or inhibition of neuronal cell death in a mammal is underdeveloped.

**(6) The Quantity of Experimentation Necessary:**

The instant claims read on a method of preventing or inhibiting neuronal cell death in a mammal in all of its forms with any C-Raf inhibitor compound. As discussed above, the specification fails to provide sufficient support for complete prevention and/or inhibition, further only two compounds are demonstrated as C-Raf inhibitors. Applicant fails to provide information sufficient to practice the claimed invention, absent undue experimentation. *Genetech*, 108 F.3d at 1366 states that “a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion” and “patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable.”

Accordingly the claims are not enabled for a method of preventing or inhibiting neuronal cell death in a mammal comprising administration of C-Raf inhibitors.

***Conclusion***


Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEONARD M. WILLIAMS whose telephone number is (571)272-0685. The examiner can normally be reached on MF 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/L. M. W./  
Examiner, Art Unit 1617

/SREENI PADMANABHAN/  
Supervisory Patent Examiner, Art Unit 1617

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|--|-------------------------|---|--|
| <div>Application Number</div> <div></div> | Application/Control No. | Applicant(s)/Patent under Reexamination |  |
|  | 10/688,759              | D'MELLO ET AL.                          |  |
|  | Examiner                | Art Unit                                |  |
|  | LEONARD M. WILLIAMS     | 1617                                    |  |